

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

**ABBOTT LABORATORIES,
an Illinois corporation,**

Plaintiff,

v.

**BANNER PHARMACAPS INC.
a Delaware corporation,**

Defendant.

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Civil Action No. 07-754

ANSWER AND COUNTERCLAIMS OF BANNER PHARMACAPS INC.

Defendant Banner Pharmacaps Inc. ("Banner") hereby responds to the Complaint by Abbott Laboratories ("Abbott") as follows:

THE PARTIES

1. Upon information and belief, Banner admits the averments contained in paragraph 1.
2. Banner admits the averments contained in paragraph 2.

JURISDICTION AND VENUE

3. Banner admits that the Complaint contains averments of patent infringement that arise under the patent laws of the United States, but denies that these averments have merit. Banner also admits that 28 U.S.C. § 1338(a) grants this Court subject matter jurisdiction over civil actions arising under the patent laws of the United States.
4. Banner admits the averments contained in paragraph 4.
5. Banner admits that venue exists in this judicial district.

FACTUAL BACKGROUND

The '731 and '326 Patents

6. Upon information and belief, Banner admits the averments contained in paragraph 6.

7. Upon information and belief, Banner admits that the FDA approved Abbott's New Drug Application No. 18-723 for the product under the brand name DEPAKOTE® on or about March 10, 1983 and that DEPAKOTE® is included in the Orange Book. The averments of statutory construction do not require a response. Banner denies the remaining averments contained in paragraph 7.

8. Upon information and belief, Banner admits the averments contained in paragraph 8.

9. Upon information and belief, Banner admits the averments contained in paragraph 9.

10. Banner is without information sufficient to form a belief as to the truth of the averments contained in paragraph 10, and therefore denies them.

11. Banner is without information sufficient to form a belief as to the truth of the averments contained in paragraph 11, and therefore denies them. Banner further refers to the cited decisions for their content.

12. Upon information and belief, Banner admits the averments contained in paragraph 12

Banner Notifies Abbott Regarding the Filing of New Drug Application No. 22-152

13. Banner admits that it sent a notice to Abbott dated October 9, 1007. Banner further states that the notice speaks for itself. To the extent that there are further averments contained in paragraph 13 not addressed by the foregoing, Banner denies those averments.

14. Banner admits that a "Detailed Statement" was attached to the October 9, 2007 notice. Banner further states that the "Detailed Statement" speaks for itself. To the extent that there are further averments contained in paragraph 14 not addressed by the foregoing, Banner denies those averments.

15. Banner denies the averments contained in paragraph 15 of the Complaint, and affirmatively avers that the allegations of said paragraph are irrelevant to the claims in this action.

16. As to paragraph 16 of the Complaint, Banner refers to Exhibit C of the Complaint for its content, and affirmatively avers that the averments contained in the paragraph are irrelevant to the claims in this action. To the extent that there are further averments in paragraph 16 not addressed by the foregoing, Banner denies those averments.

COUNT 1: INFRINGEMENT OF THE '731 PATENT

17. Banner incorporates by reference its responses to paragraphs 1-16, as if fully set forth herein.

18. Paragraph 18 of the Complaint is a statement of law to which no response is required. To the extent that there are further averments contained in paragraph 18 not addressed by the foregoing, Banner denies those averments.

19. Denied.

20. Denied.

COUNT II: INFRINGEMENT OF THE '326 PATENT

21. Banner incorporates by reference its responses to paragraphs 1-16, as if fully set forth herein.

22. Paragraph 22 of the Complaint is a statement of law to which no response is required. To the extent that there are further averments contained in paragraph 22 not addressed by the foregoing, Banner denies those averments.

23. Denied.

24. Denied.

PRAYER FOR RELIEF

Banner denies that Abbott is entitled to any relief based upon its Complaint.

COUNTERCLAIMS

For its counterclaims against Plaintiff/Counterclaim-Defendant Abbott Laboratories (“Abbott”), Counterclaim-Plaintiff/Defendant Banner Pharmacaps Inc. (“Banner”) hereby states as follows:

THE PARTIES

1. Upon information and belief and as pled by Abbott, Abbott is a corporation organized under the laws of the State of Illinois, with its principal place of business at Abbott Park, Illinois 60064.

2. Banner is a corporation organized under the laws of the State of Delaware, with its principal place of business at 4100 Mendenhall Oaks Parkway, Suite 301, High Point, NC 27265.

JURISDICTION AND VENUE

3. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and under the common law.

4. This Court has original jurisdiction over the subject matter of these Counterclaims pursuant to 28 U.S.C. §§ 1331, and 1338(a) and (b).

5. This Court has personal jurisdiction over Abbott because Abbott has availed itself of the rights and privileges of this forum by suing Banner in this judicial district and because Abbott conducts substantial business in, and has regular and systematic contact with, this judicial district.

6. Venue for these Counterclaims is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and 1400(b).

**COUNTERCLAIM I: DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF THE '731 AND '326 PATENTS**

7. On information and belief, Abbott is the holder of approved new drug application (“NDA”) No. 18-723 granted by the Federal Food and Drug Administration (“FDA”) for Depakote® (divalproex sodium) delayed release tablets, indicated for treatment of epileptic seizures (“Abbott’s product”).

8. On information and belief, Abbott is the owner of U.S. Patents No. 4,988,731 (“the ’731 patent”) and U.S. Patent No. 5,212,326 (“the ’326 patent”). Abbott has submitted these patents for listing with FDA, asserting that they claim Abbott’s product.

9. Banner has submitted § 505(b)(2) new drug application 21-152 (“Banner’s NDA”) to FDA for regulatory approval to sell valproic acid delayed release capsules, also for treating epileptic seizures (“Banner’s product”). Valproic acid is a chemical entity related to

divalproex sodium. FDA advised Banner to rely on Abbott's product as the reference listed drug for Banner's product.

10. In its NDA, Banner submitted a "Paragraph IV" certification that Banner's product does not infringe the '731 patent or the '326 patent.

11. The '731 patent is not infringed by Banner's product because of the requirement in all claims of the patent for an oligomer having a 1:1 molar ratio of sodium valproate and valproic acid. Banner's product does not contain an oligomer of sodium valproate and valproic acid. Banner's product contains only valproic acid. For this reason, Banner's product does not infringe, either literally or under the doctrine of equivalents, the '731 patent.

12. The '326 patent is not infringed by Banner's product because of the requirement in all claims of this patent, as well, for an oligomer having a 1:1 molar ratio of sodium valproate and valproic acid. Banner's product does not contain an oligomer of sodium valproate and valproic acid. Banner's product contains only valproic acid. For this same reason, Banner's product does not infringe the '326 patent, either literally or under the doctrine of equivalents.

13. Abbott has commenced this action against Banner, alleging that Banner's NDA containing the aforesaid Paragraph certification is an act of infringement concerning the '731 patent and the '326 patent.

14. There is an actual, substantial, and continuing justiciable controversy between Banner and Abbott regarding infringement of the '731 patent and the '326 patent.

15. Banner is entitled to a judicial declaration that any making, use, sale, offer for sale, marketing, or importation of the Banner product has not infringed, does not infringe, and will not infringe the '731 patent or the '326 patent, either directly or under the doctrine of equivalents.

SECOND COUNTERCLAIM:

UNFAIR COMPETITION

16. Banner repeats the allegations contained in paragraphs 1 through 15 of its Counterclaims as though fully set forth herein.

17. On information and belief, Abbott lacked upon filing their Complaint, and lacks today, a bona fide, objectively reasonable and good faith basis to allege infringement.

18. On information and belief, Abbott filed this action without substantial justification for the wrongful and anticompetitive purpose of invoking the 30-month statutory delay which prohibits the FDA from approving Banner's NDA 22-152 for 30 months, in order to prevent the FDA from issuing final approval to Banner's NDA 22-152. Further, by improperly precluding the final approval until the expiration of the patents, Abbott was able to invoke the statutory six-month extension of monopoly for pediatric uses, which it could not have been able to obtain but for the improper filing of this action.

19. Banner has suffered and will continue to suffer economic harm as the result of the above Abbot's actions.

20. Abbott's improper filing of this action was a willful and malicious effort to knowingly cause significant economic harm to Banner, therefore warranting punitive and enhanced damages.

WHEREFORE, Banner prays for judgment:

A. Dismissing the Complaint with prejudice and entering judgment thereon in favor of Banner;

- B. On Counterclaim I,
- (a) declaring and adjudging that Banner's product, and the making, use, sale, offer for sale, marketing, or importation of Banner's product; does not infringe the '731 patent or the '326 patent;
 - (b) permanently enjoining Abbott, its officers, agents, directors, servants, employees, subsidiaries, and assigns, and all those acting under the authority of or in privity with them or with any of them, from asserting or otherwise seeking to enforce the '731 and '326 patents against Banner;
 - (c) declaring that this case is an exceptional one pursuant to 35 U.S.C. § 285 and awarding Banner its reasonable attorneys fees and costs incurred in this action;
- C. On Counterclaim II, judgment for damages actually sustained by Banner;
- D. Costs and expenses of this litigation, including reasonable attorneys' fees;
- E. Such other relief as the Court deems just and proper.

Dated: January 28, 2008

By: /s/ AnnaMartina Tyreus

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DEMAND FOR JURY TRIAL

Banner hereby demands a trial by jury on all issues so triable.

CERTIFICATE OF SERVICE

I hereby certify that on January 28, 2008, I caused a true copy of the foregoing Defendant Banner Pharmacaps Inc.'s Answer and Counterclaims to be served on the following by e-mail and was electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to the following:

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